IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **Wave 2 TVT cases (*Pamela Bailey, et al. v. Ethicon, Inc.*, Case No. 2:12-cv-01700, only)**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF JOYE K. LOWMAN, M.D.

As a threshold matter, Plaintiffs note that their motion (Dkt. 2449) applies to all Wave 2 TVT cases and then includes on their Exhibit 1 four cases to which the motion applies. But only one case listed on Exhibit 1 involves a TVT device—*Pamela Bailey*, Case No. 2:12-cv-01700. The other three cases do not apply because they do not involve TVT products or are no longer active.[1] Thus, Plaintiffs' motion—and this response—affect only the *Bailey* case.

Even so, Plaintiffs' challenges to Dr. Lowman's general-causation opinions should be rejected. Plaintiffs seek to exclude or limit Dr. Lowman's general-causation opinions on three grounds. First, they claim, incorrectly, that Dr. Lowman's TVT opinions do not apply to Ms. Bailey because Ms. Bailey was implanted with a TVT-O device. Second, Plaintiffs argue that Dr. Lowman is not qualified to render opinions about the safety and effectiveness of mesh products because she has never designed an implantable medical product, and instead relies on her clinical experience and review of the literature. And lastly, they claim that she is not qualified to render opinions about the "adequacy" of the TVT-O IFU. Plaintiffs' motion should be denied because:

[1] The case involving Plaintiff Margaret Frazier, Case No. 2:12-cv-01731, has been dismissed.

- **Ms. Bailey was implanted with the TVT product.** As more fully explained in the response addressing Dr. Lowman's specific-causation opinions, Ms. Bailey was implanted with a TVT device, making Dr. Lowman's TVT opinions relevant and within the scope of her expertise.

- **Dr. Lowman is qualified to opine about the safety and effectiveness of the TVT.** Dr. Lowman is an experienced urogynecologist sub-specialty certified in female pelvic-floor medicine and reconstructive surgery. Her extensive training, experience, and review of the relevant medical literature qualify her to offer opinions about the safety and effectiveness of the TVT. As this Court has repeatedly held, a urogynecologist's reliance on her clinical experience and review of relevant literature is a reliable method for forming opinions on the safety and efficacy of mesh products.

- **The challenged IFU opinion is not an "adequacy" opinion.** The IFU opinions elicited addressed IFUs in general, not the TVT or TVT-O IFU in particular, and had nothing to do with the "adequacy" of any particular IFU.

Plaintiffs' challenges to Dr. Lowman's opinion testimony are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Defendants Ethicon, Inc., and Johnson & Johnson (Ethicon) therefore ask that Plaintiffs' motion be denied.

ARGUMENTS AND AUTHORITIES

I. Dr. Lowman's TVT opinions are relevant and admissible.

Plaintiffs claim that Dr. Lowman's opinions should be excluded because Ms. Bailey was implanted with a TVT-O device, not a TVT device. Pls.' Mem. (Dkt. 2452) at 4. As more fully explained in Ethicon's contemporaneously filed response to Plaintiffs' motion to exclude Dr. Lowman's specific-causation opinions (Case No. 2:12-cv-01700), incorporated here, Plaintiffs are incorrect. Ms. Bailey was implanted in 2001—years before the TVT-O was on the market, so there is no dispute that Ms. Bailey was implanted with a TVT device, not a TVT-O. *See* Defs.' Resp. to Pls.' Mot. to Exclude the Specific Opinions of Joye K. Lowman, M.D. at 2. Dr. Lowman's extensive experience implanting TVT devices, and her opinions formed from that experience, are therefore well within her expertise and relevant.

II. Dr. Lowman's safety and efficacy opinions satisfy the *Daubert* standard and are therefore admissible.

A. Dr. Lowman is qualified to provide safety and efficacy opinions.

A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for [the expert's] opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court in particular has made clear that a physician can draw upon her clinical experience and review of relevant literature to give an opinion on the safety and efficacy of polypropylene mesh products. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of polypropylene mesh products).

Dr. Lowman offers the same kind of opinion here—*i.e.*, that polypropylene mesh products, including the TVT, are safe and effective for use in patients. *See* Ex. C to Pls.' Mot. (Dkt. 2449-4), Lowman Report at 7, 11-13. And she has the necessary qualifications to do so. She is a board-certified, fellowship-trained female pelvic reconstructive surgeon. Ex. B to Pls.' Mot. (Dkt. 2449-3), Lowman 6/24/16 Dep. Tr. 12:3-6, 60:22-24. She started the urogynecology department at Kaiser Permanente in Atlanta, Georgia and has been the lead for urogynecology services there since its inception. *Id*. at 13:5-7, 13:15-17. Her practice is devoted solely to female pelvic medicine and reconstructive surgery; it is all she does. *Id*. at 60:22-61:1.

Dr. Lowman's experience with polypropylene mesh products is extensive. She has performed more than 2,800 surgical procedures to treat both stress urinary incontinence and pelvic organ prolapse, including performing native tissue repairs, abdominal sacrocolpopexies, and implanting various devices for both stress urinary incontinence and pelvic organ prolapse. Ex. C to Pls.' Mot. (Dkt. 2449-4), Lowman Report at 1-2. Of those 2,800 procedures, 1,300

involved polypropylene mesh. *Id*. at 2. Since the early 2000s, she has implanted over 850 mid-urethral slings from various manufacturers using various approaches, of which approximately 800 have been TVT devices. *Id.*; *see also* Ex. B to Pls.' Mot. (Dkt. 2449-3), Lowman 6/24/16 Dep. Tr. 23:9-12, 53:11-15, 54:1-13; *see also id*. at 15:8-10, 37:10-12. And she has done so without patient complaints of dyspareunia, pelvic pain, erosion, infection, or contraction. Ex. B to Pls.' Mot. (Dkt. 2449-3), Lowman 6/24/16 Dep. Tr. 26:22-27:1; *see also* Ex. C to Pls.' Mot. (Dkt. 2449-4), Lowman Report at 10. Besides performing surgical implant procedures, she has also performed approximately six revision surgeries for midurethral slings. Ex. B to Pls.' Mot. (Dkt. 2449-3), Lowman 6/24/16 Dep. Tr. 44:11-14.

Dr. Lowman's extensive experience with stress urinary incontinence, and the use of mesh products to treat it, sufficiently qualifies her to render opinions on the safety and efficacy of mesh products. Contrary to Plaintiffs' argument (Pls.' Mem. (Dkt. 2452) at 5-7), the law does not require Dr. Lowman to have expertise designing mesh products to be qualified to give an opinion on the safety and efficacy of these products. *See Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *6-7 (S.D.W. Va. May 5, 2016). Nor does the law require Dr. Lowman to be a materials scientist or have examined pathology microscopically to be qualified to give an opinion on the safety and efficacy of polypropylene mesh. *Tyree*, 54 F. Supp. 3d at 579-80, 585.

Instead, as this Court has repeatedly made clear, a urogynecologist like Dr. Lowman whose practice focuses on pelvic floor dysfunction, and, as a result, has performed hundreds of mesh procedures, is sufficiently qualified to give the safety and efficacy opinions she offers here. *See, e.g.*, *Frankum v. Boston Scientific Corp.*, No. 2:12-cv-00904, 2015 WL 1976952, at *34 (S.D.W. Va. May 1, 2015) (finding defense expert sufficiently qualified where the expert "has performed over 800 sling procedures, and her clinical practice focuses on pelvic floor

dysfunction"); *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va. 2013); *Tyree*, 54 F. Supp. 3d at 585 (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products).

Plaintiffs' arguments to the contrary find no support under *Daubert* or this Court's rulings and should therefore be rejected.

B. Dr. Lowman's safety and efficacy opinions are based on well-recognized methodologies.

Despite her extensive clinical experience and background, Dr. Lowman's opinions are not premised solely on that experience, but on her review of the medical literature as well. Dr. Lowman cites extensive peer-reviewed medical literature that, in addition to her experience, establishes that TVT products are safe and effective for treatment of stress urinary incontinence. *See* Ex. C to Pls.' Mot. (Dkt. 2449-4), Lowman Report at 7-8, 12-13, 16-17 (referencing scientific literature throughout her report to support her opinions); *see also generally* Ex. 1, Lowman Reliance List in Addition to Materials Referenced in Report.

As consistently established, an expert's reliance on peer-reviewed scientific literature is an acceptable methodology. *Tyree*, 54 F. Supp. 3d at 552 ("[T]he review of other professionals' research can form a sound and reliable basis for an expert opinion. Here, [the expert] conducted a thorough review of others' medical research in establishing his opinions."); *see also Frankum*, 2015 WL 1976952, at *34 (finding expert's methodology sufficiently reliable where the expert "cites numerous studies and academic papers throughout her expert report to support her opinions").

Dr. Lowman's reliance on similar medical research cited throughout her report and supplemental reliance list is no different. *See* Ex. C to Pls.' Mot. (Dkt. 2449-4), Lowman Report at 7-8, 12-13, 16-17; Ex. 1, Lowman Reliance List in Addition to Materials Referenced in

Report. And she is conversant with the medical literature in her field and has relied on that literature not only in forming her opinions here but also as a means of caring for her patients. *See, e.g.*, Ex. B to Pls.' Mot. (Dkt. 2449-3), Lowman 6/24/16 Dep. Tr. 28:17-33:3, 34:12-36:16, 52:16-53:10, 99:23-101:7, 111:8-112:2. Thus, Dr. Lowman brings the same "intellectual rigor" in testifying as she employs outside the courtroom. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

Plaintiffs nonetheless take issue with Dr. Lowman's opinions because she conducted no studies herself. Pls.' Mem. (Dkt. 2452) at 5-7. But, as this Court recognized, observations made by surgeons in their clinical practice are "obviously" not the "type of opinion [that is] subject to testing or peer review." *Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *29 (S.D.W. Va. May 6, 2015). Even so, "[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability." *Daubert*, 509 U.S. at 593. So too this Court has recognized that publication "is not dispositive." *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, at *31 (S.D.W. Va. May 19, 2016). Consequently, that Dr. Lowman may not have published in this area or otherwise conducted any studies does not render her unqualified to give the safety-and-efficacy opinions she offers here.

At bottom, Dr. Lowman has the expertise required to provide opinions on the safety and efficacy of TVT products, and has provided reliable bases for those opinions. Her opinion testimony is therefore admissible.

III. Dr. Lowman's IFU testimony is admissible.

Plaintiffs take issue with Dr. Lowman's IFU testimony—elicited by Plaintiffs' counsel—as to Dr. Lowman's perceptions about an IFU's purpose and how an IFU is used by physicians in general. *See* Pls.' Mem. (Dkt. 2452) at 7-8. Plaintiffs frame this argument as an "adequacy"

argument, but the testimony Plaintiffs point to in their memorandum says nothing about IFU adequacy. Instead, Dr. Lowman is expressing her opinion, in response to Plaintiffs' counsel's questioning, about the purpose of an IFU in general, why certain information is included, and how an IFU is used or should be used in practice. *Id.* Although "[d]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings" (*Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015)), Dr. Lowman's IFU testimony challenged by Plaintiffs here is not an "adequacy" opinion at all, much less whether the TVT IFU, in particular, is adequate.

Plaintiffs' reliance on this Court's decision in *Sederholm v. Boston Scientific Corp.*, No. 2:13-cv-12510, 2016 WL 3282587 (S.D.W. Va. June 14, 2016), does nothing to advance their argument. In that case, the Court excluded testimony from a defense expert who offered opinions that the warnings were adequate merely because they included risks that the expert observed in his own practices. *Id.* at *13. The opinion testimony excerpted at page seven of Plaintiffs' memorandum offers no such opinion. *Sederholm* is wholly irrelevant.

But even if Dr. Lowman's nonspecific, general IFU testimony can be construed as an "adequacy" opinion—and it is not—Dr. Lowman is well-qualified to render this opinion. She has performed in excess of 1,300 mesh surgical procedures, of which 800 or so are TVT procedures alone; she has considerable experience from which to offer opinions about how she in particular and her colleagues in general use and rely on a product's IFU.

At bottom, Plaintiffs' challenge to Dr. Lowman's IFU opinions is baseless. She is sufficiently qualified to give the IFU testimony Plaintiffs challenge. Plaintiffs' IFU argument should be rejected.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on August 8, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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